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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,193	11/29/2000	Chih-Ming Chen	300.1023	6199

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/02/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,193

Applicant(s)

CHENG ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 21 January 2003.

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-4, 6-20 and 24-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4, 6-20 and 24-34 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114 and prior art filed 01/21/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said antihyperglycemic drug" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 6-20 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott (US 3,621,097).

Scott discloses a method of treating mental illness where the method comprises administration of a composition that comprises dimethyl biguanide (abstract, claim 1 and column 3, line 70 to column 4, line 10 and claims 1-4). Scott discloses that the composition may include disintegrators, lubricants, diluents, binders, flavors, suspending agents, surfactants and

Art Unit: 1615

preservatives and further suggests that the dimethyl biguanide can be prepared for oral administration in the form of sustained-release tablets, lozenges, capsules, dragees, pills, powders, aqueous and non-aqueous suspensions, suppositories for rectal administration and aqueous or non-aqueous solutions for parenteral administration (column 4, lines 13-37). The formulation in example 2 contains dimethyl biguanide hydrochloride, which is the hydrochloride salt form of metformin. A search in the registry file of STN indicates that dimethyl biguanide is metformin.

The instant invention is directed to a sustained release formulation comprising metformin or pharmaceutically acceptable salt. The recitation that the formulation provides therapeutic levels of the drug in a human patient is a property of the formulation and the property of a composition is not separable from the composition. The instant claims do not recite any specific dose that would exclude the metformin or dimethyl biguanide formulation of Scott from having the property of providing a therapeutic plasma level in a 24-hour level when Scott's formulation is administered to treat mental. The influence of food on the bioavailability of metformin is a property of metformin. Regarding the dissolution profile of the instant metformin formulation, the metformin formulation of Scott would also have a dissolution profile and since no amount or dose of metformin is recited in the instant claims, the dissolution profile recited in the instant claims appears not to be unique to the formulation of the instant claims.

Scott teaches the instant metformin formulation except that the sustained release nature of Scott's formulation is suggested. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation of Scott as a sustained release dosage form because Scott suggest formulating a sustained release dosage form. One

Art Unit: 1615

having ordinary skill in the art would have been motivated to prepare the formulation of Scott as a sustained release dosage form with the expectation that when the dosage form is administered to treat mental illness the drug level in the plasma will be sustained for a period of time at an effective level to treat the condition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
May 14, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600